Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
3/10/2026
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:04 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 8 voting members present. A quorum was maintained for the entire meeting.

Confidentiality: The Chair reminded the committee that while redacted meeting minutes will be made public, the information discussed should be considered confidential to protect the identity of individuals and the competitiveness of proprietary or technical information.

Conflict of Interest: The Chair asked the committee if any members needed to declare a conflict of interest with respect to any matter on the agenda. The Chair notified committee members that if they had a conflict of interest, they must leave the room during the final discussion and voting on that IBC submission.

2 Attendees

Committee Members Present

Lewis Bowen (Campus Operations)	Biological Safety Officer
Benjamin Gantner (Medicine)	Chair
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert
Anna Huppler (Pediatrics)	R/SNA Technology Expert
Eric Jensen (Research Office)	Animal Containment Expert
Tyce Kearl (Medicine)	R/SNA Technology Expert HGT Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Matthew Surdel (Medicine)	R/SNA Technology Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting
Lezi E (Cell Biology Neurobiology and Anatomy)	R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert

Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

02/10/2026 (Zoom)

Motion:	Minutes Approved
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8

4 New Business

1. IBC Standard – *IBC Membership*

   The Chair presented the Institutional Biosafety Committee (IBC) Standard entitled *IBC Membership* and reminded the IBC when the Standard was created, the IBC at that time determined that members could serve a limit of two consecutive three-year terms. The Chair proposed removing that requirement to allow members to serve additional consecutive terms. He clarified that removing this requirement would not mean that IBC members would have to continue serving, simply that they would have the option to remain on the IBC. The Chair asked if there were any questions or concerns. There being none, he asked the Committee to consider this change over the coming month, and there would be an official vote at the next IBC meeting.

2. Revised IBC Standard – *IBC Application Requirements*

   The Chair presented the revised Institutional Biosafety Committee (IBC) Standard: *IBC Application Requirements* to the IBC. He reminded the Committee that this Standard was approved at the January 13, 2026 meeting and allows Principal Investigators (PIs) to have consortium-like IBC applications that could cover multiple studies, including studies under the supervision of collaborators. This revision is being brought to the Committee to clarify this standard also applies to shared Animal Use Applications (AUAs) and includes the requirements for IBC applications that support shared AUAs. The Chair asked if there were any questions or concerns. There being none, a Committee member made a motion to approve the revised IBC Standard and was seconded. The Committee voted to approve the revised IBC Standard: *IBC Application Requirements*.

3. Position Statement – *PPE Requirements for BSL2+ Work*

   The Chair reminded the Institutional Biosafety Committee (IBC) of the discussion at the February 10, 2026 IBC Meeting regarding BSL2+ work in locations where BSL2 or lower work is also occurring. The concern with this arrangement is that staff only working with BSL2 or lower agents do not have or use respirators. The Biosafety Office evaluated the situation and recommended that work with BSL2+ agents can be done without respirators as long as that work is confined to biological safety cabinets (BSCs). He then presented the Position Statement entitled *PPE Requirements for BSL2+ Work*, which records the IBC's decision that a respirator would not be required for BSL2+ work performed in BSCs, but all other personal protective equipment (i.e. double gloves, dedicated lab coat, and surgical mask or face shield) would still be required, and PIs would need to submit an amendment to their IBC application to reflect this change. After reviewing the Position Statement, a Committee member asked whether this update would also apply to animal BSL2+ (ABSL2+) work. After brief discussion, the Committee confirmed that the updated requirements would also apply to ABSL2+ work. A Committee member asked if a clarification could be made that respirators would be required for all individuals within the room where BSL2+ work is being conducted if it is performed outside of a BSC. After discussion, the IBC agreed this was an appropriate addition. Upon a motion duly made by a Committee member and seconded, the IBC

voted to approve the Position Statement entitled*PPE Requirements for BSL2+ Work* with the requested clarification.

4. Revised IBC Standard – *Review of IBC Applications*

   The Chair presented the revised Institutional Biosafety Committee (IBC) Standard – *Review of IBC Applications* to the Committee and explained that the changes in the Standard would allow IBC renewals and amendments that do not include substantially new hazards to be reviewed and approved by the Biological Safety Officer (BSO) without having to be reviewed by the full IBC. These IBC renewals and amendments would ultimately be approved after undergoing the standard Pre Review process. The BSO requested the statement "to approved clinical trials" be removed from the final sentence to clarify that this review route could apply to IBC applications that support both basic research and clinical trials. A Committee member asked if review by the Animal Containment Expert (ACE) would still be required if there were no changes to this work. After discussion, the Committee agreed that the BSO and Biosafety Office could determine if ACE review would be required and forward renewals or amendments as necessary. The Committee also confirmed that the BSO could route an amendment or renewal for full Committee review if he felt it was appropriate. The Chair asked if there were further questions or concerns. There being none, he called for a vote. Upon a motion duly made by a Committee member and seconded, the Committee voted to approve the revised IBC Standard entitled *Review of IBC Applications*.

5. Administrative Report

   The Chair asked the Committee Members to review the Administrative Report and then invited discussion. No concerns were raised.

6. Exempt Rodent Report

   The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20120742_REN05 Pluripotent stem cells for studying human development, disease, and treatment

Principal Investigator:	Allison Ebert
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
NIH Guidelines:	Section III-D-1, Section III-D-2, Section III-D-4, Section III-E, Section III-F-1, Section III-F-8 (C-I), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and went on to describe the study. The Principal Investigator (PI) uses pluripotent stem cells (PSC) to study human development, disease, and treatments of neurodegenerative disorders. The PI will use human PSC (HPSC) and patient derived samples (blood, urine, cerebral spinal fluid (CSF)) to understand cell death and biomarkers of disease. Genes will be delivered to cells using adeno-associated virus (AAV) and lentivirus to reveal mechanisms of disease. Additionally, cytomegalovirus (CMV) and human herpesvirus 6A (HHV6) viral infections will be studied using stem cells and fetal progenitor cells. Studies will also be completed in whole eyes of non-human primates as well as cells to understand retinal diseases. The Primary and Secondary Reviewers noted that the protocol is well written, and the risk assessment and mitigation strategies are appropriate. The Reviewers requested a few changes, including providing a brief description of the use of Sendai virus, clarifying which animal

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species will receive stem cell transplantation and how that will be administered, and updating the attached standard operating procedures to agree with information provided in the IBC application. The Reviewers also requested that a study team member renew their bloodborne pathogens training. The Animal Containment Expert (ACE) had no additional comments. The Biological Safety Officer (BSO) requested a few changes, including that the PI clarify which viral vectors will be used for expression of oncogenes and confirm whether the lab is following standard procedures for accidental exposures to biological materials. After brief discussion, upon a motion duly made by the Chair and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20140045_REN04 T cell biology

Principal Investigator:	Calvin Williams
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
NIH Guidelines:	Section III-D-4, Section III-F-8 (C-I), Section III-F-8 (C-II), Section III-F-8 (C-VII), Section III-F-8 (C-VIII)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and went on to explain the study. The Principal Investigator (PI) studies how regulatory T cells (Tregs) shape immune tolerance and inflammatory disease. In vivo work includes Treg depletion using diphtheria toxin, induction of autoimmune myositis using CFA/IFA plus pertussis toxin, and Enterococcus faecalis colonization via drinking water (antibiotic-marked/engineered strains) with subsequent stool and GI tissue collection. Leftover infant blood samples will be used for flow cytometry to investigate the development of the immune system. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary reviewers had noted that the protocol is well written. The Reviewers requested a few changes, including that the PI clarify how recombinant DNA is used in the study, confirm whether cells will be transported, and include a risk assessment for the rDNA used in this study. The Animal Containment Expert (ACE) had no additional comments. The Biological Safety Officer (BSO) stated the PI will need to confirm whether the lab is following standard procedures for accidental exposures to biological materials. After brief discussion, upon a motion duly made by the Chair and seconded, the Committee voted to approve this renewal pending the requested changes.

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IBC20230027_REN01 Protein structure and function

Principal Investigator:	Francesca Marassi
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
NIH Guidelines:	Section III-D-1, Section III-E, Section III-F-8 (C-I), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to elaborate on the study. The Principal Investigator (PI) studies protein structure and function to provide insights into diseases of aging and host-pathogen interactions. Experiments include engineering of Escherichia (E.) coli and mammalian cells with recombinant DNA, studies of purified proteins, and growth and transformation with plasmids of Salmonella enterica. The study uses microorganisms (Salmonella enterica subspecies typhimurium, E. coli (K-12 and multiple B-strains)), recombinant DNA (multiple plasmids for expression of non-oncogenic proteins, one of which is administered to human cells), and human source materials (HEK293 and Expi293 cells). The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are adequate. The Reviewers had one minor request that the PI clarify whether unloading of centrifuge rotors will occur in a biological safety cabinet (BSC) or a fume hood. The Biological Safety Officer (BSO) noted that a study team member needs to renew bloodborne pathogens training and stated the PI will need to confirm whether the lab is following standard procedures for accidental exposures to biological materials. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20140024_REN04 Hillard Lab Protocols

Principal Investigator:	Cecilia Hillard
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
NIH Guidelines:	Section III-E, Section III-F-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Principal Investigator's (PI's) overall objective is to explore the role of endocannabinoid signaling in regulating brain function, including the production of small lipid transmitting molecules and the cellular, circuit and behavioral responses following receptor activation. This signaling network is involved in several diseases. The PI's lab uses pertussis toxin to inhibit cannabinoid receptor signaling, tetrodotoxin to inhibit sodium channel firing, and adeno-associated virus (AAV) to study synthesis and release of endocannabinoids. The PI's lab examines endocannabinoid concentrations as well as lipids and stress hormones in human blood. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are comprehensive and detailed. The Reviewers requested a few minor updates, including that the PI update the lab locations, confirm that human blood and

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serum will be handled in a biological safety cabinet (BSC), and provide updated documents for the toxins. The Biological Safety Officer (BSO) stated the PI will need to confirm whether the lab is following standard procedures for accidental exposures to biological materials. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20250043 Discarded Materials

Principal Investigator:	Ashraf El-Meanawy
Motion:	Tabled
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
NIH Guidelines:	Section III-D-4, Section III-E, Section III-F-2, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Reviewer noted that this application was being brought back before the Committee after being tabled at the January 13, 2026 IBC Meeting. The Principal Investigator (PI) proposes to use discarded human kidneys and blood products for various physiologic and molecular studies. The PI also wishes to test the impact of free light chains (FLCs) in tubular cell function and to deliver lipid-encapsulated RNA, including small interfering RNA (siRNA), or DNA to cell lines or live animals to overexpress or silence genes of interest. The application uses recombinant DNA (morpholino oligos and lipid encapsulated RNA) and human source materials. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated several requests for clarifications or additions remain unanswered, new entries require additional clarification, and the Reviewers stated the work described in the application is difficult to understand. The Chair proposed that the PI meet with a member of the Biosafety Office to discuss the requested changes before he can resubmit the application. If the next submission of the current application does not sufficiently allow for informed review to determine that it is in compliance with NIH and institutional standards, the application will be disapproved. The Reviewers, Animal Containment Expert (ACE), and Biological Safety Officer (BSO) concurred with the Chair. After brief discussion, upon a motion duly made by the Chair and seconded, the Committee voted to table this application.

6 Adjournment

There being no further business, the meeting was adjourned at 2:36 pm. The next regularly scheduled meeting will be held on Tuesday, April 14, 2026 at 1:00 pm via Zoom.